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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,459	08/26/2003	Thomas Yung-Hui Chien	1001.2205101	5094

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/648,459	Applicant(s) CHIEN ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10 and 12-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 12-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/08/08 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the protective sheath as in claim 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 17 objected to because of the following informalities: Claim 17 dependent from claim 14 recites "the cooling" in line 1. There is lack of antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4-10, 14-16, 18, 19, 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski (6,579,305) in view of Fischell (US 5,976,153).

6. Lashinski discloses a stent delivery system (for example Fig. 2) comprising: an inner tube (tube defining guide wire lumen) comprising a proximal end and a distal end, the inner tube being disposed within an outer tube (22) with an annular space (25)

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disposed therebetween, a distal tip (see Fig. 2, portion of inner shaft that extends beyond balloon) a heating element (saline fluid indicated by arrows C4:L45-54) positioned around the inner tube proximal to the distal tip, the outer tube comprising a proximal end and a distal end, the distal end of the outer tube being disposed proximally to the distal tip of the inner tube and defining a distal end diameter, the distal end of the outer tube being connected to a balloon (27) which extends between the distal end of the outer tube and the distal tip of the inner tube, the balloon overlying the heating element (arrows), and an expandable stent (28) positioned around the balloon and disposed between the distal end of the outer tube and the proximal edge of the distal tip, wherein the stent is formed of a stent material having a shape memory transition temperature lower than the an elevated temperature produced by the heating element so that the stent expands in response to the heating provided by the heating element (C1:L43-62; C4:L43-54), Regarding claim 4: the balloon is also connected to the distal tip of the inner tube (see Figure 2). Regarding claims 5 and 24: the stent is crimped onto the balloon (C4:L2). Regarding claims 6 and 25: the stent comprises nitinol (C1:L45). Regarding claim 7 and 26: the stent is a self-expanding stent (C1:L35-62; C4:L51 where the stent is shape memory nitinol and expanded by influence of heat). Regarding claim 9: the distal tip of the inner tube is tapered (see Fig. 2).

7. Lashinski does not disclose that the edge diameter of the distal tip of the inner tube and the distal end diameter of the outer tube are equal to or greater than a maximum outer diameter of the stent in an unexpanded form. However, Fischell discloses a stent delivery device with improved pushability in order to better cross tight

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lesions (C3:L10-47). Fischell discloses an inner tube (12) having a distal tip (24) with a proximal edge diameter (not edge where sheath abuts distal tip as well as edge where radiopaque marker (13d) abuts distal tip) and an outer tube (14p) having a distal end diameter, wherein both diameters are equal to or greater than a maximum outer diameter of the stent in an unexpanded form (see Fig. 3). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this structure taught by Fischell into the stent delivery device of Lashinski in order to improve pushability and torqueability of the delivery device. Regarding claim 10, Fischell teaches a distal radiopaque marker (13d) disposed proximal to the distal tip. Fischell discloses a proximal radiopaque marker (13p) which is located proximally to the outer tube rather than distally. However, it would have been obvious matter of design choice to one having ordinary skill in the art at the time of the invention to change the location of the marker depending on the needs of the physician and the location of the stent delivery in the body.

8. Regarding claim 8: Lashinski modified by Fischell do not explicitly disclose that the balloon comprises an elastomeric material. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to substitute elastomeric material so that the balloon can maintain a reduced profile after being deflated. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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9. Regarding claim 14: Lashinski further disclose the method steps of inserting, heating, deflating and withdrawing (C4:L43-54; C6:L25-35). Regarding claim 15: the heating of the stent the balloon is heated and partially inflated (C4:L43-54). Regarding claim 16, during the inserting step, the balloon and stent are cooled (it is inherent that the balloon and stent are cooled during inserting since the warm saline is not applied until the device reaches the site of stenosis (C4:L45-46). Regarding claim 18: the heating is performed using warm saline solution delivered through the annular space and into the balloon (see arrows fig. 2). Regarding claim 19: the heating is performed using a heating element (the warm saline is considered the heating element).

10. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell as applied to claim 16 above, and further in view of Rabkin (US 6,676,692)

11. Lashinski and Fischell does not disclose the use of a cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cool fluid during delivery to ensure that the stent does not expand prematurely (CC18:L13-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

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12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell as applied to claim 19 above, and further in view of Healy (US 6607553).

13. Lashinski modified by Fischell does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring the temperature is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

14. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell as applied to claim 19 above, and further in view of Layne (US 6,096,027).

15. Lashinski modified by Fischell does not disclose a protective sheath. However Layne discloses that it is old and well known to incorporate a protective sheath around a stent delivery device in order to ensure sterilization prior to delivering the device into the body (C2:L30-66). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this feature to achieve the same advantage.

16. Claims 3, 12, 13, 20, 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell as applied to claims 1 and 14 above, and further in view of Kasprzyk (US 5,035,694).

17. Lashinski modified by Fischell does not disclose that the heating element is a coil connected to a power line and a return line through which current is supplied to the coil. However Kasprzyk discloses the use of a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon (C6:L16-22). The heating element is connected to a power supply (33) via a power line and a return line which are insulated (C4:L52-C5:L25). While, Kasprzyk does not disclose the use of supplying heat for expanding a stent, but rather discloses the function of supplying heat for the purpose, it would have been obvious to one having ordinary skill in the art at the time of the invention to look to Kasprzyk for the purpose of finding an alternative way of supplying heat to the invention of Lashinski modified by Fischell. Doing so would allow the operator more control over the change in temperature and thus more control over the expansion rate of the stent thereby ensuring accurate placement of the stent during delivery.

18. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell and Kasprzyk as applied to claim 27 above, and further in view of Rabkin (US 6,676,692)

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19. Lashinski modified by Fischell and Kasprzyk does not disclose the use of a cool saline solution to cool the stent and balloon during delivery. However Rabkin discloses that it is well known in the art to use a cool fluid during delivery to ensure that the stent does not expand prematurely (CC18:L13-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this same feature to achieve the same advantage.

20. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell as applied to claim 27 above, and further in view of Healy (US 6607553).

21. Lashinski modified by Fischell and Kasprzyk does not further disclose a thermocouple located on the distal end of the inner tube for monitoring the temperature. However Healy discloses the use of a thermocouple for monitoring the temperature is high enough to transition the stent without being too high too damage the tissue (C8:L52-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a thermocouple for the same advantage. Regarding the location of the thermocouple it would have been obvious to one having ordinary skill in the art at the time the invention was made relocate the thermocouple to location that provides the most efficient feedback for its use since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

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22. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lashinski in view of Fischell and Kasprzyk as applied to claim 27 above, and further in view of Layne (US 6,096,027).

23. Lashinski modified by Fischell and Kasprzyk does not disclose a protective sheath. However Layne discloses that it is old and well known to incorporate a protective sheath around a stent delivery device in order to ensure sterilization prior to delivering the device into the body (C2:L30-66). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this feature to achieve the same advantage.

Response to Arguments

24. Applicant's arguments with respect to pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/1/09